



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/482,933	06/07/95	NORTHRUP	M 07043/015002

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HM31/0331

EXAMINER	
MARSCHEL, A	

ART UNIT	PAPER NUMBER
1634	# 8

DATE MAILED: 03/31/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/482,933</b>	Applicant(s) <b>Northrup et al.</b>
	Examiner <b>Marschel, Ardin</b>	Group Art Unit <b>1634</b>

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 81-87 and 93-105 is/are pending in the application.

~~On the above, claim(s) 1-80 and 88-92 have been canceled.~~

~~Claims withdrawn from consideration~~

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 81, 82, 85-87, and 93-105 is/are rejected.

Claim(s) 83 and 84 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). /4 sheets

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed.

Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claims 93-105 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 93 and 94, lines 1 and 3, respectively cite the phrase "preselected polynucleotide". This phrase is NEW MATTER because consideration of the entire instant disclosure as filed has failed to reveal written basis for this phrase. The closest

citation appears to be on page 4, lines 1-6, of the instant specification but notably lacks any "preselected..." disclosure. This phrase also contains NEW MATTER due to its adding vagueness and indefiniteness. Specifically, it is unclear what preselection criteria or procedure is meant thereby. Is the preselection a target preselection? Is it a sample preselection? Is it a large target preselection wherein a shorter segment is amplified via appropriate primers? In summary, the phrase adds NEW MATTER both due to lack of written basis as filed and due to a lack of clarity regarding what is meant. Claims 93, 96, 100, and 103; lines 22, 12, 13, and 3; respectively; as well as at other claim citations also contain this NEW MATTER phrase.

Claims 94 and 103 are rejected, as discussed below, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94, lines 6-7, cites the phrase "said polynucleotide". This phrase lacks clear antecedent basis because it is unclear whether the "said" points to the "preselected polynucleotide" or the "sample polynucleotide". Claim 103 contains a similar phrase without clear antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 81, 82, 85-87, and 93-105 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Wilding et al. (P/N 5,498,392).

Wilding et al. discloses in the abstract and the remainder of the patent devices for amplification reactions including detection means, especially PCR type reactions, which read on the instant claims. These devices are microfabricated from semiconductor, e.g., silicon, wafers. Claims 1-20 of the patent reference are almost identical to the instant claims. Volume ranges for reaction volumes include the picoliter range as described in column 4, lines 6-9. In column 4, lines 28-35, electrical resistance heating means is provided near the reaction chamber for temperature control. Glass or plastic (inherently elastomeric) coverslips are described in column 8, lines 59-62, such that optical detection may be practiced.

Claims 83 and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 30, 1998

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER